K130862

SECTION 5- 510(k) SUMMARY
for
Cavitron® Prophy-Jet® Air Polishing Prophylaxis System

DENTSPLY

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1. **Submitter Information:**

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JUL 2 3 2013

Contact Person: Helen Lewis
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Date Prepared: March 19, 2013

2. **Device Name:**
   - Proprietary Name: Cavitron® Prophy-Jet® Air Polishing Prophylaxis System
   - Classification Name: Ultrasonic scaler
   - CFR Number: 872.4850
   - Device Class: II
   - Product Code: ELC

3. **Predicate Device:**

The proposed Cavitron® Prophy-Jet® Air Polishing Prophylaxis System is substantially equivalent to the following legally marketed devices:

- Dentsply International Cavitron® SPS Ultrasonic Scaler and Prophy-Jet®, K970342, product code ELC.
- Dentsply International Cavitron® RF Ultrasonic Scaler with Sterimate Handpiece, K052334, product code ELC.
- EMS Electro Medical Systems, S.A. EMS Air-Flow Master Piezon, K110173, Product Codes ELC, EFB, EJR
- Satelec Air-N-Go, K110379, Product Code EFB

The following accessories used with the proposed Cavitron® Prophy-Jet® Air Polishing Prophylaxis System were previously cleared by FDA:

- Cavitron® PROPHY-JET® Sodium Bicarbonate Prophy Powder (K970342)
- Cavitron® JET-Fresh® Aluminum Trihydroxide Prophy Powder (K014188)
- Cavitron® JET-Mate™ detachable sterilizable handpiece (K023697)
- Cavitron® Jet Air Polishing Insert (K041141)

4. Description of Device:

The Cavitron® Prophy-Jet® Air Polishing Prophylaxis System is an air polishing unit that delivers an air/water/powder mixture at the air polishing insert tip that polishes the tooth enamel without direct contact of the device. The system is used with water-soluble prophy powders such as Cavitron® PROPHY-JET® Sodium Bicarbonate Prophy Powder (K970342) or Cavitron® JET-Fresh® Aluminum Trihydroxide Prophy Powder (K014188) (for patients with low sodium requirements). Updated design features on the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System include a Tap-On™ Wireless Foot Pedal, prophy mode auto cycles, an illuminated diagnostic display, automated purge function, Cavitron® JET-Mate™ detachable sterilizable handpiece (K023697), and a swivel handpiece cable with more precise lavage control. Upon installation, the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System unit is connected to external air and water lines, as well as an AC power cord.

5. Intended Use:

The Cavitron® Prophy-Jet® Air Polishing Prophylaxis System is designed for use in general prophylaxis and periodontal treatments and other areas of operative dentistry. It can also be used for:

- Stain removal,
- Prophylaxis of orthodontic patients,
- Preparing tooth surfaces prior to bonding and sealant procedures, and
- Implant debridement

6. Identification of Risk Analysis Method:

Risk analysis was performed on the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System utilizing an FMEA process based on ISO 14971. The results of the risk analysis performed on the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System concluded that all device design controls and process controls will be able to mitigate known potential failures and effects. In addition, performance testing and electrical safety testing were performed to mitigate other potential risks.

7. Description of Safety and Substantial Equivalence:

7.1 Technological Characteristics:

The technological characteristics of the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System are very similar to the predicate devices; Cavitron® SPS Ultrasonic Scaler and Prophy Jet (K970342) and Cavitron® RF Ultrasonic Scaler with Sterimate Handpiece (K052334). All devices operate by the use of a foot pedal. The foot pedal in the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System and the predicate Cavitron® RF Ultrasonic Scaler with Sterimate Handpiece (K052334) can be connected to the system with a wire or by wireless means. The foot pedals of the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System and the predicate Cavitron® SPS Ultrasonic Scaler and Prophy Jet (K970342) have a two position operation. The first position is for rinsing, and second position is for air polishing. The Cavitron® Prophy-Jet® Air Polishing Prophylaxis System and the predicate Cavitron® SPS Ultrasonic Scaler and

Prophy Jet (K970342) both utilize the same water-soluble air polishing prophy powders and air polishing insert. The Cavitron® Prophy-Jet® Air Polishing Prophylaxis System and the predicate Cavitron® RF Ultrasonic Scaler with Sterimate Handpiece (K052334) both have a handpiece which can be removed to autoclave. Both the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System and the predicate Cavitron® SPS Ultrasonic Scaler and Prophy Jet (K970342) have a selector pointer on the top of the powder bowl which determines the amount of prophy powder which can be delivered to the patient. Both systems require the same input air and water pressure to function correctly. The Cavitron® Prophy-Jet® Air Polishing Prophylaxis System and the predicate Cavitron® RF Ultrasonic Scaler with Sterimate Handpiece (K052334) have lavage control on the handpiece to select a water flow rate for system operation,. All lavage controls deliver the same range of water flow to the patient.

The proposed Cavitron® Prophy-Jet® Air Polishing Prophylaxis system has added indications for stain removal, prophylaxis of orthodontic patients, preparing tooth surfaces prior to bonding and sealant procedures, and implant debridement. Although these indications are not included in the cleared indications of the air polishing predicate Cavitron® SPS Ultrasonic Scaler and Prophy Jet (K970342), they are cleared indications for newer air polishing devices. Specifically, the Satelec Air-N-Go dental prophylaxis handpiece (cleared under premarket notification K110379) and the EMS Medical Systems Air-Flow Master Piezon (cleared under premarket notification K110173) include indications for the removal of, "soft deposits and areas of discoloration", the preparation of teeth for, "conventional dental procedures such as the placement of composite fillings", "plaque and stain removal for orthodontic patients", and "cleaning of implant fixtures" and abutments. There are also multiple literature references that make a case for the safety of cleaning implants using an air polishing device.

7.2 Non-Clinical Performance Data:

Performance testing focused on verification of design, stain removal, enamel abrasion, function and safety of the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System. Below is a summary of the testing performed:

- IEC 60601-1-2 Medical Electrical Equipment PART 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility (2007)
- IEC 60601-1 Medical Electrical Equipment Part 1:General requirements for basic safety and essential performance (2005)
- FDA – Guidelines for the Content of Premarket Submissions for Software Contained in Medical Devices – Software Validation
- Internal specification and testing for handpiece operation, including lavage control
- Internal specification and testing for autocycle operation
- Internal specification and testing for indicator lights and user interface functionality
- Internal specification and testing for radio frequency distance for foot pedal
- Internal specification and third party testing for stain removal and abrasion

The results of these performance tests support the substantial equivalence of the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System..

7.3 Clinical Performance Data:

No human clinical data has been provided to support substantial equivalence.

7.4 Conclusion as to Substantial Equivalence:

The similarities in design, function, safety and intended use of the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System with the legally marketed predicate devices support substantial equivalence. The performance and safety data support the substantial equivalence of the Cavitron® Prophy-Jet® Air Polishing Prophylaxis System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2013

DENTSPLY International, Incorporated
C/O Ms. Helen Lewis
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405-0872

Re: K130862
Trade/Device Name: Cavitron® Prophy-Jet® Air Polishing Prophylaxis System
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: June 19, 2013
Received: June 20, 2013

Dear Ms. Lewis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K130862

Device Name: Cavitron® Prophy-Jet® Air Polishing Prophylaxis System

Indications for Use:

The Cavitron® Prophy-Jet® Air Polishing Prophylaxis System is designed for use in general prophylaxis and periodontal treatments and other areas of operative dentistry. It can also be used for:

- Stain removal,
- Prophylaxis of orthodontic patients,
- Preparing tooth surfaces prior to bonding and sealant procedures, and
- Implant debridement

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
2013.07.23 14:48:30 -04'00'

for M. Susan Runner, DDS, MA

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130862